

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Brandon J. Fetterolf  
Group : 1642  
Applicants : Leszek Wojnowski et al.  
Application No. : 10/070,587  
Confirmation No. : 7615  
Filed : March 8, 2002  
For : POLYMORPHISMS IN THE HUMAN CYP3A4 AND  
CYP3A7 GENES AND THEIR USE IN DIAGNOSTIC  
AND THERAPEUTIC APPLICATIONS

New York, New York  
March 29, 2007

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicants hereby make of record  
the following documents, copies of which are submitted herewith:

FOREIGN PATENT DOCUMENTS

<u>Publication No.</u>	<u>Publication Date</u>
WO 99/13106	March 18, 1999

04/02/2007 HDESTA1 00000052 061075 10070587  
03 FC:1806 180.00 DA

### OTHER REFERENCES

Beaune et al., "Isolation and sequence determination of a cDNA clone related to human cytochrome P-450 nifedipine oxidase", *Proceedings of the National Academy of Sciences of the United States of America*, 83:8064-8068 (1986).

Eiselt et al., "Identification and functional characterization of eight CYP3A4 protein variants", *Pharmacogenetics*, 11:447-458 (2001).

Hashimoto et al., "Gene structure of CYP3A4, an adult-specific form of cytochrome P450 in human livers, and its transcriptional control", *European journal of biochemistry / FEBS*, 218:585-595 (1993).

Wang et al., "Inhibitory anti-CYP3A4 peptide antibody: mapping of inhibitory epitope and specificity toward other CYP3A isoforms", *Drug Metabolism and Disposition*, 27(2):167-172 (1999).

Westlind et al., "Interindividual Differences in Hepatic Expression of CYP3A4: Relationship to Genetic Polymorphism in the 5'-Upstream Regulatory Region", *Biochemical and Biophysical Research Communications*, 259:201-205 (1999).

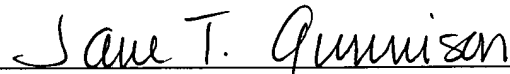
EMBL-Bank Accession No. A1638117, "ts50e10.x1 NCI\_CGAP\_Ut1 Homo sapiens cDNA clone IMAGE:2232042 3' similar to gb:J04182 LYSOSOME-ASSOCIATED MEMBRANE GLYCOPROTEIN 1 PRECURSOR (HUMAN);, mRNA sequence."

The aforementioned references are listed on the accompanying Form PTO/SB/08A (submitted in duplicate). These references were first cited in a communication from the European Patent Office in a counterpart foreign application. Copies of these references are enclosed with this Statement.

Applicants further request that the cited documents be (1) fully considered by the Examiner during the course of examination of this application, and (2) printed on any patent issuing from this application. Additionally, applicants request that a copy of Form PTO/SB/08A, as considered and initialed by the Examiner, be returned with the next communication.

In accordance with 37 C.F.R. § 1.97 (c), this Statement is accompanied by a check for \$180.00, which is the fee as set forth in 37 C.F.R. § 1.17(p). The Director is hereby authorized to charge payment of any additional fees required in connection with the accompanying Supplemental Information Disclosure Statement, or credit any overpayment, to Deposit Account No. 06-1075, Order No. 003747-0069. A duplicate copy of this Statement is enclosed.

Respectfully submitted,

A handwritten signature in cursive script, reading "Jane T. Gunnison", is written over a horizontal line.

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PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary) Sheet 1 of 1				<b>Complete if known</b>	
				Application Number	10/070,587
				Filing Date	March 8, 2002
				First Named Inventor	Leszek Wojnowski
				Art Unit	1642
				Examiner Name	Brandon J. Fetterolf
				Attorney Docket Number	VOS-30

U.S. PATENT DOCUMENTS					
Examiner initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Country	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>1</sup> - Number <sup>2</sup> - Kind Code <sup>3</sup>				
		WO 99/13106	03/18/1999	PCT		

NON PATENT LITERATURE DOCUMENTS			
Examiner initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published	T <sup>6</sup>
		BEAUNE et al., "Isolation and sequence determination of a cDNA clone related to human cytochrome P-450 nifedipine oxidase", <i>Proceedings of the National Academy of Sciences of the United States of America</i> , 83:8064-8068 (1986).	
		EISELT et al., "Identification and functional characterization of eight CYP3A4 protein variants", <i>Pharmacogenetics</i> , 11:447-458 (2001).	
		HASHIMOTO et al., "Gene structure of CYP3A4, an adult-specific form of cytochrome P450 in human livers, and its transcriptional control", <i>European journal of biochemistry / FEBS</i> , 218:585-595 (1993).	
		WANG et al., "Inhibitory anti-CYP3A4 peptide antibody: mapping of inhibitory epitope and specificity toward other CYP3A isoforms", <i>Drug Metabolism and Disposition</i> , 27(2):167-172 (1999).	
		WESTLIND et al., "Interindividual Differences in Hepatic Expression of CYP3A4: Relationship to Genetic Polymorphism in the 5'-Upstream Regulatory Region", <i>Biochemical and Biophysical Research Communications</i> , 259:201-205 (1999).	
		EMBL-Bank Accession No. A1638117, "ts50e10.x1 NCI_CGAP_Ut1 Homo sapiens cDNA clone IMAGE:2232042 3' similar to gb:J04182 LYSOSOME-ASSOCIATED MEMBRANE GLYCOPROTEIN 1 PRECURSOR (HUMAN);, mRNA sequence."	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.